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USPTO RECD/PCT/PTO 17 NOV 2000

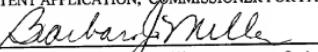
PATENT

Attorney Reference No. SPI/HER (4289*120)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF EXPRESS MAIL
(37 C.F.R. § 1.10)

I HEREBY CERTIFY THAT THIS PAPER OR FEE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE, EXPRESS MAIL POST OFFICE TO ADDRESSEE* UNDER 37 C.F.R. § 1.10, BEARING EXPRESS MAIL LABEL NO. EE617838188US ON THIS 17 TH DAY OF NOVEMBER, 2000 AND IS ADDRESSED TO: BOX PATENT APPLICATION, COMMISSIONER FOR PATENTS, WASHINGTON, D.C. 20231.

 Barbara J. Miller
(Signature of person mailing paper or fee) Barbara J. Miller
(Name of Person mailing paper or fee)

LE ET AL.	:	INTERNATIONAL FILING DATE: MAY 19, 1999
SERIAL NO: TO BE ASSIGNED	:	INTERNATIONAL APP. NO. PCT/US99/11072
	:	EXAMINER:
FOR: CO-PROCESSED COMPOSITIONS OF : ACIDS AND WATER SOLUBLE CRYSTALLINE COMPOUNDS AND RELATED PRODUCTS AND METHODS		ART UNIT:

Box Patent Application
Commissioner for Patents
Washington, D.C. 20231

**TRANSMITTAL OF APPLICATION PAPERS TO U.S.
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. § 371 (37 CFR 1.494 OR 1.495)**

This transmittal letter is based upon Form PTO-1390.

The above-identified applicant has filed an International Application under the PCT and hereby submit(s) to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

International Application No. PCT/US99/11072

1. This is the FIRST submission of items concerning a filing under 35 U.S.C. §371.
2. This is the SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. §371.
3. This is an express request to begin national examination procedures (35 U.S.C. §371(f)) at any time rather than delay.
4. A proper Demand for International Preliminary Examination (IPE) was made to the appropriate Authority (IPEA) by the 19th month from the earliest claimed priority date.
5. A copy of the International Application as amended (35 U.S.C. §371(c)(2)) -
(a) is transmitted herewith (required when not transmitted by International Bureau).
(b) has been transmitted by the International Bureau.
(c) is not required, as the application was filed in the United States Receiving Office (RO/US).
6. A translation of the International Application into the English language WILL FOLLOW.
7. Amendments to the (specification and) claims of the International Application under PCT Article 19 (35 U.S.C. §371 (c)(3))
(a) are transmitted herewith (required if not transmitted by the International Bureau).
(b) have been transmitted by the International Bureau.
(c) have not been made; however, the time limit for making such amendments has NOT expired.
(d) have not been made and will not be made.
(e) will be submitted with the appropriate surcharge.
8. A translation of the amendments to the claims (and/or the specification) under PCT Article 19 (35 U.S.C. §173(c)(3)) is enclosed or will be submitted with the appropriate surcharge.
9. An executed Oath or Declaration/Power of Attorney of the inventor(s) (35 U.S.C. §371(c)(4)) has been filed with the USPTO (filed on August 9, 1999). If the patent office should require an updated Oath or Declaration/Power of Attorney, applicants request that they be so notified.

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International Application No. PCT/US99/11072

10. A translation of at least the Annexes to the IPE Report under PCT Article 36 (35 U.S.C. §371(c)(5)) is enclosed.

Items 11. to 16. below concern other document(s) or information included:

11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98 is enclosed.
12. An Assignment is enclosed for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31. is included.
13. **A FIRST preliminary amendment is enclosed. IT IS REQUESTED THAT THE FILING FEES FOR THE CLAIMS BE CALCULATED AFTER THE CLAIM AMENDMENTS IN THE PRELIMINARY AMENDMENT HAVE BEEN ENTERED.**
14. A substitute specification (including claims, abstract, drawing) is enclosed.
15. A change of Power of Attorney and/or address letter is enclosed.
16. Other items of information:

This application is being filed pursuant to 37 CFR 1.494(c) or 1.495(c), and any missing parts will be filed within the time period set in accordance with 35 C.F.R. 1.495(C).

22 months from the priority date under 37 CFR 1.494(c), or

32 months from the priority date under 37 CFR 1.495(c).

The undersigned attorney is authorized by the International application and by the inventors to enter the **National Phase** pursuant to 37 CFR 1.494(c) or 1.495(c).

The following additional information relates to the International Application:

- Receiving Office: US
 IPEA (if filing under 37 CFR 1.495): US
 Priority/Benefit claim(s) (35 USC §§ 120, 119 (e), 365):

PCT/US99/11072 filed May 19, 1999 claiming the benefit of the May 19, 1998 filing date of US 09/080,970 under 35 USC §120.

- A copy of the International Search Report is
 enclosed.

International Application No. PCT/US99/11072

- attached to the copy of the International Application.
- A copy of the Receiving Office Request Form is enclosed.
17. Small Entity Form

The fee calculation is set forth below.

FEE CALCULATION

NOTE: IT IS REQUESTED THAT THE FILING FEES FOR THE CLAIMS BE CALCULATED AFTER THE CLAIM AMENDMENTS IN THE PRELIMINARY AMENDMENT HAVE BEEN ENTERED.

- [x] A check in payment of the filing fee, calculated as follows, is attached (37 CFR 1.492)

Basic Fee (37 CFR 1.492(a)(1)) \$690.00

Total Number of claims
in excess of (20) times \$18 \$72.00

Number of independent claims
in excess of (3) times \$80 \$160.00

Fee for multiple dependent
claims \$270 \$0.00

Surcharge of \$130.00 for furnishing the oath or declaration
later than 30 months from the earliest claimed priority date
(37 CFR 1.492(e))..... \$0.00

TOTAL FILING FEE \$922.00

Kindly send us the official filing receipt.

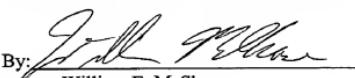
The Commissioner is hereby authorized to charge any additional fees which may be required or to credit any overpayment to Deposit Account No. 03-2775. This is a "general authorization" under 37 CFR 1.25(b), except that no automatic debit of the issue upon allowance is authorized. This letter is being submitted in triplicate.

International Application No. PCT/US99/11072

Respectfully submitted,
CONNOLLY BOVE LODGE & HUTZ LLP

Date: November 17, 2000

By:



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Attorney Reference No. SPI/HER
(4289*120)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

LE ET AL. : INTERNATIONAL
FILING DATE: MAY 19, 1999

SERIAL NO: TO BE ASSIGNED : INTERNATIONAL
APP. NO. PCT/US99/11072

: EXAMINER:

FOR: CO-PROCESSED COMPOSITIONS OF : ART UNIT:
ACIDS AND WATER SOLUBLE
CRYSTALLINE COMPOUNDS AND
RELATED PRODUCTS AND METHODS

Box Patent Application
Commissioner for Patents
Washington, D.C. 20231

"Express Mail" mailing label number: EE617838188US

Date of Deposit: November 17, 2000

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Box Patent Application, Commissioner for Patents, Washington, D.C. 20231 by

Barbara J. Miller
(Signature of person mailing paper or fee)

Barbara J. Miller
(Name of Person mailing paper or fee)

PRELIMINARY AMENDMENT

Sir:

Prior to calculating the filing fees for the present application and prior to examining the above-identified application on the merits, please amend the application as follows.

In the Specification:

Page 1, before the first line of text, insert the following new section:

-- Cross-Reference to Related Applications

The present patent application is a §371 of International Application No. PCT/US99/11072 filed on May 19, 1999 and claiming priority to U. S. patent application serial no. 09/080,970 filed on May 19, 1998 in the names of Anh Si Le et al. --

In the Claims:

Please cancel claims 1-77, 79-82, 84-87, 89, 91 and 98-114 without prejudice or disclaimer.

Please amend claims 78 and 97 as follows.

78. (Amended) A co-processed composition [consisting essentially of] comprising at least one water-soluble crystalline compound selected from the group consisting of [sugar alcohols, sugars and derivatives thereof] mannitol, erythritol, isomalt and lactitol, and at least one acidulant selected from the group consisting of phosphoric acid, citric acid, malic acid, fumaric acid, tartaric acid, ascorbic acid and lactic acid, wherein said water-soluble crystalline compound is present in said co-processed composition in an amount of from 80 to 99 percent by weight and said at least one acidulant is present in said co-processed composition in an amount of from 1 to 20 percent by weight, further wherein said co-processed composition is in the form of granules or agglomerates.

97. (Amended) The co-processed composition of claim 78, wherein the at least one water-soluble crystalline compound is mannitol and the at least one acidulant is phosphoric acid.

Please add new claims 115-128 as follows.

-- 115. A co-processed composition consisting essentially of at least one water-soluble crystalline compound selected from the group consisting of mannitol, erythritol, isomalt and lactitol, and at least one acidulant selected from the group consisting of phosphoric acid, citric acid, malic acid, fumaric acid, tartaric acid, ascorbic acid and lactic acid, wherein said water-soluble crystalline compound is present in said co-processed composition in an amount of from 80 to 99 percent by weight and said at least one acidulant is present in said co-processed composition in an amount of from 1 to 20 percent by weight, further wherein said co-processed composition is in the form of granules or agglomerates.

116. A co-processed composition consisting essentially of at least one water-soluble crystalline compound selected from the group consisting of mannitol, erythritol, isomalt and lactitol, and at least one acidulant selected from the group consisting of phosphoric acid, citric acid, malic acid, fumaric acid, tartaric acid, ascorbic acid and lactic acid, wherein said water-soluble crystalline compound is present in said co-processed composition in an amount of from 80 to 99 percent by weight and said at least one acidulant is present in said co-processed composition in an amount of from 1 to 20 percent by weight, further wherein said co-processed

composition is in the form of granules or agglomerates of said at least one water-soluble crystalline compound and said at least one acidulent with the at least one acidulent being trapped or contained within the at least one water-soluble crystalline compound in the granules or agglomerates.

117. A co-processed composition consisting essentially of at least one water-soluble crystalline compound selected from the group consisting of mannitol, erythritol, isomalt and lactitol, at least one acidulent selected from the group consisting of phosphoric acid, citric acid, malic acid, fumaric acid, tartaric acid, ascorbic acid and lactic acid, and water, wherein said water-soluble crystalline compound is present in said co-processed composition in an amount of from 80 to 99 percent by weight, said water is present in said co-processed composition in an amount of from 0.01 to 2 percent by weight, and the remainder of said co-processed composition is said at least one acidulent, further wherein said co-processed composition is in the form of granules or agglomerates.

118. A co-processed composition consisting essentially of at least one water-soluble crystalline compound selected from the group consisting of mannitol, erythritol, isomalt and lactitol, at least one acidulent selected from the group consisting of phosphoric acid, citric acid, malic acid, fumaric acid, tartaric acid, ascorbic acid and lactic acid, and water, wherein said water-soluble crystalline compound is present in said co-processed composition in an amount of from 80 to 99 percent by weight, said water is present in said co-processed composition in an amount of from

0.01 to 2 percent by weight, and the remainder of said co-processed composition is said at least one acidulent, further wherein said co-processed composition is in the form of granules or agglomerates of said at least one water-soluble crystalline compound, said at least one acidulent and water with the at least one acidulent being trapped or contained within the at least one water-soluble crystalline compound in the granules or agglomerates.

119. Pharmaceutical product, food product or confectionery product containing the co-processed composition of claim 78 and an acid-sensitive additive.

120. Pharmaceutical product, food product or confectionery product of claim 119, wherein said acid-sensitive additive is a flavor.

121. Pharmaceutical product, food product or confectionery product containing the co-processed composition of claim 115 and an acid-sensitive additive.

122. Pharmaceutical product, food product or confectionery product of claim 121, wherein said acid-sensitive additive is a flavor.

123. Pharmaceutical product, food product or confectionery product containing the co-processed composition of claim 116 and an acid-sensitive additive.

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124. Pharmaceutical product, food product or confectionery product of claim 123, wherein said acid-sensitive additive is a flavor.
125. Pharmaceutical product, food product or confectionery product containing the co-processed composition of claim 117 and an acid-sensitive additive.
126. Pharmaceutical product, food product or confectionery product of claim 125, wherein said acid-sensitive additive is a flavor.
127. Pharmaceutical product, food product or confectionery product containing the co-processed composition of claim 118 and an acid-sensitive additive.
128. Pharmaceutical product, food product or confectionery product of claim 127, wherein said acid-sensitive additive is a flavor. - -

REMARKS

The parent international application contained claims 1-114. In the present Preliminary Amendment, claims 1-77, 79-82, 84-87, 89, 91 and 98-114 have been cancelled without prejudice or disclaimer. The specification and claims 78 and 97 have been amended. New claims 115-128 have been added. It is respectfully requested that the filing fees for the present application be calculated after the present amendments to the claims have been entered and before starting examination on the merits of the instant patent application.

Respectfully submitted,
CONNOLLY BOVE LODGE & HUTZ LLP

By


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09/70043

CO-PROCESSED COMPOSITIONS OF ACIDS AND WATER SOLUBLE
CRYSTALLINE COMPOUNDS AND RELATED PRODUCTS AND METHODS

5 This application is a continuation-in-part of U.S. Patent Application Serial No. 09/080,970, filed May 19, 1998.

BACKGROUND OF THE INVENTION

10 1. Field of the Invention

The present invention relates to co-processed compositions of acids and water-soluble crystalline compounds, and in particular, to shelf-stable comestible, confectionery, pharmaceutical, and dentifrice products which contain these co-processed compositions. The present invention also relates to methods of making these co-processed compositions, products containing the same, and methods of making and using such products.

15 2. The Related Art

Acidulants or acids are used in comestible and dentifrice products for a variety of reasons. For example, acid is taught for use in chewing gum to increase saliva production for the treatment of xerostomia or dry mouth (U.S. Patent No. 5,151,270, Ream et al.) or for use during exercising (U.S. Patent No. 4,906,455, Hoerman). Acid has also been used in chewing gum to soften plaque on teeth (U.S. Patent No. 4,400,372, to Muhler et al.). Acidulants function as flavor enhancers as well, and when provided at optimal levels significantly improve the release of flavor in confectionery products, such as hard candies, gummy candies, chewing gum and the like.

20 However, adding oxidative acids to comestible or dentifrice products is known to quickly oxidize acid-sensitive additives, such as flavors, to the detriment of the comestible or dentifrice product. For example, the perception of flavor in an acid-containing chewing or bubble gum substantially diminishes in quality after about 2 weeks in storage. The perception of undesirable flavor notes is also of utmost concern in the confectionery industry, as well as industries producing baked goods, dairy products, beverages and the like. A need exists for products in which undesirable flavor notes are reduced or inhibited.

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Protecting additives in comestible or dentifrice products from other components in the products has often been done by methods which segregate the additive from other components in the product. For example, flavors have been segregated by encapsulation of a flavorant in media such as elastomeric matrix, polymeric medium, gelatin, wax, hydroxypropylmethylcellulose, polyethylene, fat, starch, sugar, zein, or a gum such as gum arabic, xanthan, and locust bean.

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However, encapsulation of additives such as flavors is time consuming and expensive. Further, the encapsulation process and parameters can change the character of the flavor (certain peaks present in the gas chromatographic spectrum of the flavor can be lost upon encapsulation) and some techniques of encapsulation may even preclude the release of flavor in the final product. While encapsulation may protect the flavor from an oxidative acid, encapsulation is not the ideal method for protecting the flavor because of the inhibition (or prevention) of the release of flavor caused by encapsulation. This inhibition caused by encapsulation results in a delay of the initial flavor impact which is important for consumer acceptability in products such as chewing gum. A need also exists, therefore, for a process for protecting acid-sensitive additives (e.g., alkaline ingredients such as certain flavoring compounds) from acids or acidulents in comestible, pharmaceutical, and dentifrice products.

SUMMARY OF THE INVENTION

An object of the present invention is to provide a method of minimizing the degradation of an acid-sensitive additive by at least one acidulent (e.g., an acid) in a low-moisture comestible or dentifrice product which contains the at least one acidulent. In one aspect, the method comprises preparing the product with the at least one acidulent in the form of a co-processed composition; wherein the co-processed composition is prepared by co-processing the at least one acidulent with at least one water-soluble crystalline compound independently chosen from the group consisting of sugar alcohols, sugars, and derivatives thereof.

Another object of this invention is to provide a method of removing or preventing the deposition of plaque on teeth. In one aspect, the method comprises regularly chewing a chewing gum; wherein the gum comprises a gum base, an abrasive, and at least one acidulent, wherein the at least one acidulent is in the form of a co-processed composition, and wherein the co-processed composition is prepared by co-processing the at least one acidulent with at least one water-soluble crystalline compound independently chosen from the group consisting of sugar alcohols,

sugars, and derivatives thereof.

A further object of the present invention is to provide a method of increasing salivation. In one aspect, the method comprises the step of chewing a low-moisture acid-containing comestible product; said product comprising the at least one acidulent in the form of a co-processed composition, wherein said co-processed composition is prepared by co-processing the at least one acidulent with at least one water-soluble crystalline compound independently chosen from the group consisting of sugar alcohols, sugars, and derivatives thereof.

5 A further object of the present invention is to provide a comestible product comprising at least one acidulent in the form of a co-processed composition with at least one water-soluble crystalline compound independently chosen from the group consisting of sugar alcohols, sugars, and derivatives thereof.

10 Another object of the present invention is to provide a co-processed composition consisting essentially of at least one water-soluble crystalline compound selected from the group consisting of sugar alcohols, sugars and derivatives thereof, and at least one acidulent. In one aspect, the co-processed composition is in the form of granules or agglomerates. In another aspect, the co-processed composition is in the form of powder.

15 Another object of the present invention is to provide a comestible or dentifrice product comprising an abrasive and at least one acidulent; wherein the at least one acidulent is in the form of a co-processed composition prepared by co-processing the at least one acidulent with at least one water-soluble crystalline compound independently chosen from the group consisting of sugar alcohols, sugars, and derivatives thereof.

20 Yet another object of the instant invention is to provide a process of making a co-processed composition consisting essentially of at least one water-soluble crystalline compound selected from the group consisting of sugar alcohols, sugars and derivatives thereof, and at least one acidulent. In one aspect, the process comprises the steps of mixing the at least one water-soluble crystalline compound selected from the group consisting of sugar alcohols, sugars and derivatives thereof, at least one acidulent and water to form a mixture; forming the mixture into granules or agglomerates; and removing at least a portion of the water from the granules or agglomerates. Preferably, the forming occurs in a wet granulation or agglomeration process.

25 30 A further object of our invention is to provide a pharmaceutical product, food product or confectionery product containing a co-processed composition consisting essentially of at least

one water-soluble crystalline compound selected from the group consisting of sugar alcohols, sugars and derivatives thereof, and at least one acidulent. Preferably, the at least one acidulent is selected from the group consisting of phosphoric acid and malic acid.

Another object is to provide a pharmaceutical product, food product or confectionery product that contains at least one alkaline ingredient and a co-processed composition consisting essentially of at least one water-soluble crystalline compound selected from the group consisting of sugar alcohols, sugars and derivatives thereof, and at least one acidulent.

An additional object is to provide a hard candy; a jam, jelly or other soft filling for a food product or confectionery product; or a baked product, that contains a co-processed composition consisting essentially of at least one water-soluble crystalline compound selected from the group consisting of sugar alcohols, sugars and derivatives thereof, and at least one acidulent.

Further objects of the present invention are set forth in the appended claims of the instant application.

In a preferred embodiment of the present invention, the at least one water-soluble crystalline compound is mannitol.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

It has been discovered that acidulents (e.g., acids) may be segregated from a comestible, confectionery, pharmaceutical, or dentifrice product containing acid-sensitive additives by adding the acidulent(s) to the product in the form of a co-processed composition. As long as the co-processed composition is kept in a low moisture environment and prepared with components which are low in moisture, the acidulent(s) will remain in the co-processed composition, segregated from the acid-sensitive additive, thereby enhancing the stability of the additive in the product (and therefore the stability of the product itself). Release of the acidulent(s) from the co-processed composition will occur upon the addition of moisture to the comestible, confectionery, pharmaceutical, or dentifrice product, for example, by adding water or by the contact of the product with the saliva in the mouth of a consumer. Moreover, co-processed compositions of the present invention may impart unique flavor and taste properties to products in which they are incorporated.

The amount of the acidulent(s) added to the crystalline compound(s) is an amount such

that after drying and grinding, the acidulent(s) is (are) present in the co-processed composition at the desired level.

The water-soluble crystalline compounds which may be used in preparing the co-processed composition are chosen from the group consisting of sugar alcohols, sugars, and derivatives and mixtures thereof. Examples are sugar alcohols such as mannitol, sorbitol, maltitol, xylitol, lactitol, erythritol, isomalt, sugars (i.e., monosaccharides, disaccharides and longer chain saccharides, for example, fructose, dextrose, maltose, lactose, D-tagatose and sucrose). Note that disaccharides and longer chain saccharides, for example sucrose, will break down into smaller saccharide components in the presence of acid, but will still be useful in the inventive co-processed composition provided that absorbed water (i.e., water absorbed by the smaller saccharide components) is removed during the preparation of the co-processed composition.

Examples of acidulents that may be co-processed with the water-soluble crystalline compound and added to the products of the present invention are inorganic and organic acids or salts thereof. Examples of inorganic acids are phosphoric acid, perchloric acid, nitric acid, hydrochloric acid, sulfuric acid, and boric acid. Examples of organic acids are saturated and unsaturated hydroxy and non-hydroxy C₁ to C₆ mono-, di-, and tribasic carboxylic acids such as citric acid, fumaric acid, tartaric acid, malic acid, succinic acid, ascorbic acid, glutaric acid, adipic acid, lactic acid, hydroxyacetic acid, glycolic acid and mixtures thereof. Examples of salts which may be used as a source of acid are alkali and alkaline earth metal salts of the inorganic and organic acids listed above, such as monobasic calcium phosphate, monobasic sodium phosphate, sodium hydrogen sulfite and sodium pyrophosphate.

Preferred co-processing methods in accordance with our invention include any granulation or agglomeration processes, preferably wet granulation or agglomeration processes, known to and practiced by those of ordinary skill.

Co-processed compositions in accordance with the present invention may exist in any form, although powder, granule, and agglomerate forms are preferred.

Co-processed compositions of the present invention can be used with low-moisture comestible, confectionery or dentifrice products in which the segregation of acidulent(s) from other components in the product is desirable. Examples of low-moisture products in which our

co-processed compositions may be used are solid or semi-solid comestible or confectionery products such as chewing gum, bubble gum, instant beverages, and frozen desserts and dentifrices such as toothpaste and dental floss. These low-moisture products generally contain water (bound and/or unbound) in the range of from about 0 to about 10 wt.%, preferably from 5 about 0 to about 5 wt.%, most preferably from about 0 to about 3 wt.%. The co-processed compositions of this invention may also find application in pharmaceutical products.

Examples of acid-sensitive additives which may be present in the comestible, pharmaceutical, or dentifrice products of the present invention are flavors, flavor enhancers, flavor masking additives, and aspartame. Examples of flavors which may be used with the present invention are natural or artificial flavors. Examples are essential oils, such as cinnamon, spearmint, peppermint, birch, and anise; fruit flavors, both natural flavors derived from the essence of fruits and artificial fruit flavors, e.g., apple, pear, peach, strawberry, cherry, apricot, orange, watermelon, banana, and bubble gum flavor; bean-derived flavors, such as coffee and cocoa; wine-derived flavors, such as curacao zin; and pungent materials, such as affinin, pepper, and mustard, and mixtures thereof. Examples of flavor enhancers are neohesperidin dihydrochalcone (NeoDHC), soy sauce, salt, talin (thaumatin) and monosodium glutamate (MSG) and other flavor enhancers known in the art. Examples of flavor masking additives are menthol and neohesperidin dihydrochalcone.

A comestible or dentifrice product of the present invention may also contain an abrasive useful in removing or preventing the deposition of plaque which has been softened by the acidulant from the teeth. Abrasives have been used in dentifrice products to clean and polish teeth and dentures and to aid in the prevention of caries. Representative patents are U.S. Patent Nos. 1,592,013 (Taylor), 2,059,396 (Ripert), 3,105,013 (Saul et al.), 3,282,792 (Fiscella), 3,378,445 (Muhler), 3,590,120 (Muhler), 4,108,979 (Muhler et al.), 4,108,981 (Muhler et al.), 25 4,122,163 (Muhler et al.), 4,400,372 (Muhler et al.), 4,428,928 (Muhler et al.), 4,828,820 (Glass et al.). In particular, a chewing gum containing an acid and an abrasive is known to be useful in removing and preventing the reformation of plaque on teeth (see U.S. Patent No. 4,400,372 to Muhler et al., which is herein incorporated by reference in its entirety). The acid is thought to soften the plaque and the abrasive to aid in the removal of the softened plaque. Co-processed 30 compositions of the present invention improve upon the acid/abrasive containing chewing gum

by improving the shelf-stability of the product.

For abrasive-containing products in which the acidulant assists in the softening of plaque, the amount of acidulant which is preferably present in the product is an amount such that when one (1) gram of the product (ground up if necessary) is placed into nine (9) milliliters of deionized water and mixed well, the pH of the water decreases to a level in the range of from about 1 to about 4.5 or 5, preferably in the range of from about 2.8 to about 3.2, a level which will soften the plaque. Where a salt is used as the acid source, a buffering agent should also be used to achieve the pH required. Examples of buffering agents are weak acids such as citric and malic acid.

Examples of abrasives which may be added to the comestible or dentifrice product of the present invention are calcined kaolin (as described in U.S. Patent No. 4,400,372, which is herein incorporated by reference in its entirety), calcined aluminum silicate, zirconium silicate, calcined and uncalcined talcs, $Mg_3Si_4O_{10}(OH)_2$, resin abrasives, barium sulfate, silica, alumina, calcium carbonate, pumice, sodium bicarbonate and mixtures thereof. The abrasives are preferably present in particles having a median diameter of less than or equal to about 2 micrometers wherein substantially all of the particles are less than about 20 micrometers in diameter. Where calcination is done, e.g., to increase the hardness of the abrasive, the calcination is preferably done at a temperature in the range of from about 1000°C to about 1100°C.

One clear benefit to a chewing or bubble gum made with a co-processed composition of the present invention is that the flavor is maintained at a consumer-acceptable level in the product for the entire shelf life of the gum (approximately 12 months).

A comestible or dentifrice product of the present invention is preferably a gum, either chewing or bubble gum. Preferred chewing or bubble gum compositions of the present invention contain the components listed in Table 1, which, however, are subject to change in view of consumer acceptability and changing consumer preferences. Additional components in the gum must not be components which will decompose the co-processed composition component, e.g., components that readily react with the acidulant in the co-processed composition or components containing a great deal of water. The amount of moisture in the gum should be in the range of from about 0 to about 10 wt.%, preferably from about 0 to about 5 wt.%, most preferably from about 0 to about 3 wt.%.

TABLE 1

<u>Component in Inventive Gum</u>	<u>Weight Percent of Inventive Gum</u>	
	<u>General</u>	<u>Preferred</u>
Gum Base	15-50	20-40
Flavor	0.5-2.5	1-2
Intense Sweetener	0.05-1.00	0.1-0.50
Bulk Sweeteners	30-50	35-45
Co-processed Composition	1-10	2-5
Liquid Softeners	0-30	2-20
Abrasive (optional)	5-30	8-20

The gum bases useful in the present invention, include those gum bases utilized for chewing gums or bubble gums. Both chewing and bubble gum bases employ a number of elastomeric materials as part thereof. Examples of these elastomeric materials are synthetic gums or elastomers such as butadiene-styrene copolymers, polyisobutylene and isobutylene-isoprene copolymers; natural gums or elastomers such as chicle, natural rubber Jelutong, balata, guttapercha, lechi caspi, sorva, guttakey, crown gum, perillo, and mixtures thereof. In addition, a non-toxic vinyl polymer, such as polyvinyl acetate and its partial hydrolyzate, polyvinyl alcohol, and mixtures thereof, may be used. The vinyl acetate polymer may possess a molecular weight (number average or weight average) ranging from about 2,000 to about 94,000. Among these, butadiene-styrene copolymer, polyisobutylene, isobutylene-isoprene copolymer or mixtures thereof, are frequently used.

The gum base usually includes an elastomer solvent, which may be selected from terpene resins, such as polymers of a-pinene or b-pinene, rosin derivatives including hydrogenated or partially hydrogenated derivatives, such as glycerol ester of polymerized rosin, alcohol esters of rosin, such as the glycerol ester of hydrogenated rosin, the pentaerythritol ester of hydrogenated rosin, the pentaerythritol ester of partially hydrogenated rosin, the glyceryl esters of partially hydrogenated rosin, the glycerol ester of rosin, and mixtures thereof.

The base may include softeners, plasticizers, and/or emulsifiers such as hydrogenated vegetable oil, cocoa butter, and natural waxes, petroleum waxes such as the polyethylene waxes

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and paraffin waxes, microcrystalline waxes with melting points higher than 80°C, and mixtures thereof. Fatty acids may also be used as softeners, and suitable fatty acids include stearic acid, palmitic acid, oleic acid, and mixtures thereof. Corn syrup, sugar alcohols such as sorbitol, mannitol and xylitol as well as hydrolyzed cereal solids may be used as softeners. The gum base also frequently includes emulsifiers, particularly those that would be compatible with the vinyl polymer, if included in the base. Particularly, lanolin, lecithin, glyceryl monostearate, fatty acid monoglycerides, diglycerides and triglycerides, glycerol triacetate, propylene glycol, propylene glycol monostearate and mixtures thereof may be used.

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The gum base may also contain thickeners, that may be employed alone or in conjunction with other softeners. The thickeners may include methyl cellulose, alginates, carrageenan, xanthan gum, gelatin, carob, tragacanth, locust bean gum, and carboxymethylcellulose.

The gum base may include fillers and texturing agents. Examples are mineral adjuvants such as calcium carbonate, magnesium carbonate, alumina, aluminum hydroxide, aluminum silicate, talc, tricalcium phosphate, and mixtures thereof.

The gum base may also include conventional components such as antioxidants, preservatives, and colorants. For example, titanium dioxide may be utilized as a colorant, and antioxidants such as butylated hydroxytoluene, butylated hydroxyanisole, propyl gallate, and mixtures thereof, may also be included.

Gum bases may be prepared for a variety of products, including conventional gums and bubble gums, and this invention is not limited to a specific gum base formulation. The above description is therefore presented for purposes of illustration only.

While various bulking agents can be used in the gum compositions, sugar alcohols are of particular value for both sugar-containing and sugarless compositions, since they also impart sweetness to the gum composition. Sugar alcohols useful in the preparation of the present gum compositions include mannitol, sorbitol, xylitol, lactitol, maltitol, erythritol, isomalt, etc., and mixtures thereof. High intensity sweeteners may also be added. Examples of high intensity sweeteners are saccharin, acesulfame potassium, aspartame, sucralose, cyclamates and others known in the art.

Sugarless chewing gum containing the co-processed acidulant/water-soluble crystalline compound composition may be made by the following procedure: A sugarless gum formula is

5 prepared by adding gum base to a jacketed sigma blade mixer. If rework is available it is added to the gum base and mixed until homogeneous. If no rework is available, this mixing step is omitted. If an abrasive is used, it is mixed into the base until homogeneous. High intensity sweetener and one or more dry water-soluble crystalline compounds are then added and mixed
10 until homogeneous; liquid softeners and other liquid polyols are added to the previous mixture and mixed until homogeneous; liquid flavor is added to the previous mixture and mixed 1-2 minutes; spray-dried or encapsulated flavors or sweeteners are added to the previous mixture and mixed 1 minute; the co-processed composition (e.g., co-processed acidulent(s) and water-soluble crystalline compound(s)) is then added to the previous mixture and mixed for approximately 1 minute to produce the gum. The gum is then removed from the mixer and formed into the desired format (either chunk, stick, pellet, tab, or ball).

15 Another embodiment of our invention is a co-processed composition consisting essentially of mannitol with an acidulent or a combination of two or more acidulents. In a preferred embodiment, a granulation is formed from a mixture of mannitol and at least one acidulent.

20 Preferred acidulents suitable for use in co-processed mannitol/acidulent compositions include citric, malic, fumaric, lactic, tartaric, adipic, and phosphoric acids, and other commercially available acidulent products known in the art. More preferably, mannitol may be co-processed with at least one acidulent selected from phosphoric acid and malic acid.

25 In a preferred embodiment, mannitol and at least one acidulent may be co-processed by a wet granulation or agglomeration process. For example, a mixture of mannitol powder and at least one acidulent is formed in a wet granulation or agglomeration process and the mixture is then processed to form granules or agglomerates. In a highly preferred embodiment, the granules or agglomerates formed during the wet granulation or agglomeration process are dried by removing at least a portion of the water that is present in the granules or agglomerates after they are formed. The dried granules or agglomerates may optionally be ground to a powder having a desired particle size or particle size distribution by any method known in the art.

30 The mannitol and the at least one acidulent may be combined in any amounts or proportions that are suitable to impart desired properties such as, for example, the formation of acceptable granules or agglomerates, the stabilization of alkaline ingredients in the final product,

or specific levels of flavor and sweetness. Preferred co-processed compositions comprise from about 80-99 percent by weight (preferably from about 85-95% by weight) mannitol and about 1-20 percent by weight (preferably from about 5-15% by weight) of the at least one acidulent, based on the total weight of the mannitol and the acidulent in the co-processed composition.

In addition, the co-processed compositions can contain small amounts of water. Specifically, in a preferred embodiment of the present invention, the co-processed composition consists essentially of mannitol, water and at least one acidulent selected from the group consisting of phosphoric acid and malic acid, wherein the mannitol is present in an amount of from about 80-99% by weight of the co-processed composition (preferably from about 85-95% by weight of the co-processed composition), the water is present in an amount of about 0.01% to 2% by weight of the co-processed composition (preferably from about 0.10% to 1% by weight of the co-processed composition, most preferably from about 0.10% to 0.5% by weight of the co-processed composition) and the remainder of the co-processed composition is the at least one acidulent. By the use of the phrase "consists essentially of" or "consisting essentially of" to describe the ingredients that are present in the co-processed composition, we intend to teach and claim that the listed ingredients (e.g., mannitol, water and at least one acidulent) are the principal or essential ingredients. This phrase does not exclude the presence of minor amounts of secondary ingredients or impurities that may be present as a part of one or more of the listed ingredients and that have no substantial effect on the properties or characteristics of the final co-processed composition.

The at least one acidulent may be in solid form or in solution when it is mixed with the mannitol. When the at least one acidulent is in the form of an aqueous solution, the total amount of water that is present in the acidulent/mannitol mixture should be below the solubility level for mannitol (i.e., about 20-22 grams per 100 milliliters of water at 25°C).

In a preferred embodiment, a co-processed composition consisting essentially of mannitol with at least one acidulent selected from phosphoric acid and malic acid demonstrates low moisture absorption. In a particularly preferred embodiment, wherein mannitol powder is co-processed with phosphoric acid, the co-processed composition demonstrates low moisture absorption, thereby preventing liquefaction of the co-processed composition into a syrup at, for example, about 37.8°C and 75% relative humidity.

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Co-processed compositions comprising mannitol that has been co-processed with at least one acidulent may be used in the formation of, for example, pharmaceutical products, food products and confectioneries, including chewing gums and jams, jellies or other soft fillings. Products formed from these co-processed compositions may be superior to products formed from traditional compositions by exhibiting beneficial properties as described herein. For example, by co-processing the mannitol and the at least one acidulent into a form wherein the at least one acidulent is trapped or contained within the mannitol, the at least one acidulent is not directly exposed to acid-sensitive ingredients (such as certain flavoring compounds) in the final product. This prevents or reduces reactions between the acidulent(s) and the acid-sensitive ingredients which can lead to the degradation of certain properties of the final product, including the flavor.

Various demonstrations of the present invention are included in the Examples immediately following. However, these Examples should be considered as illustrative only and should not be construed as limiting the scope of the present invention.

EXAMPLES

Example 1

The sugarless chewing gum Formulations A and B of the present invention were prepared with the components of Tables 2 and 3 as follows: Gum base was added to a jacketed sigma blade mixer. For Formulation A-0, rework was available and was added at this point to the gum base and mixed until homogeneous. The kaolin and standard chewing gum softeners were then added to the previous mixture and mixed until homogeneous. Half of the sorbitol powder was then added and mixed until homogeneous. Maltitol syrup (i.e., Lycasin) and glycerin were added to the mixture and mixed until homogeneous. The other half of the sorbitol powder and all of the other bulk polyol sweeteners were added and mixed until homogeneous. The high intensity sweetener(s) were then added and mixed 1-2 minutes. The liquid flavor was added and mixed for 1-2 minutes. The sweeteners and flavor extenders were then added and mixed for approximately 1 minute; the co-processed composition of Example 3 was then added to the

previous mixture and mixed for approximately 1 minute to produce the gum. The gum was then removed from the mixer and pelleted and coated with sorbitol.

TABLE 2 - Formulation A

	A-0 (%)	A-1 (%)	A-2 (%)	A-3 (%)	A-4 (%)
Commercially-available chewing gum base	31.32	37.50	36.00	37.50	39.50
Standard chewing gum softeners	0.52	0.75	0.75	0.75	1.00
Kaolin	10.00	10.00	10.00	10.00	10.00
Glycerin	3.5	3.75	3.25	3.25	3.4
Lycasin, 85% (low moisture maltitol syrup)	5.00	6.00	7.00	7.00	7.00
Liquid peppermint flavor	1.75	1.75	1.75	1.90	1.90
Powder peppermint flavor					1.00
High intensity sweetener (acesulfame-K)	0.16	0.16	0.16	0.16	
High intensity sweeteners (acesulfame-K and aspartame)					0.25
Various FDA-approved sweeteners & flavor extenders	1.30	1.30	1.30	1.30	2.15
Co-processed composition	3.75	3.7	3.7	3.75	3.75
Sorbitol powder	Balance	Balance	Balance	Balance	
Sorbitol powder and other bulk polyol sweetener for cooling effect					Balance
Total	100.00	100.00	100.00	100.00	100.00

Formulations B-1 and B-2 were prepared with the components listed in Table 3:

TABLE 3 - Formulation B

	B-1 (%)	B-2 (%)
Commercially-available chewing gum base	37.50	36.00
Standard chewing gum softeners	0.75	0.75
Kaolin	10.00	10.00
Xylitol Powder	15.00	15.00
Glycerin	3.75	3.25
Lycasin, 85% (low moisture maltitol syrup)	5.00	6.00
Liquid flavor (peppermint)	1.60	1.60
Powder flavor (menthol)	1.15	1.15
High intensity sweetener (acesulfame-K)	0.46	0.46
Various FDA-approved sweeteners & flavor extenders	1.30	1.30
Co-processed composition	3.7	3.7
Sorbitol powder	Balance	Balance
Total:	100.00	100.00

The differences between Formulations A and B are that Formulation A contains sorbitol and liquid flavor whereas Formulation B contains sorbitol and xylitol as well as both liquid and powder flavor.

Example 2

The stability of the flavor additive in chewing gum Formulations A-0 through A-4 of the present invention was demonstrated by having panelists trained to evaluate chewing gum compare the flavor of a typical acid-containing chewing gum with a chewing gum of the present invention in which the acid was co-processed with a water-soluble crystalline compound (Formulations A-0 through A-4). The control was a peppermint-flavored chewing gum combined with a free phosphoric acid. The inventive gum Formulation A is a peppermint-

flavored chewing gum containing the co-processed composition of Example 3 (i.e., in which phosphoric acid was co-processed with mannitol before addition to the chewing gum).

Before evaluation, chewing gum Formulation A-0 was subjected to accelerated aging approximating 18 weeks. The control chewing gum and chewing gum Formulations A-1 through 5 A-3 were not aged but were evaluated fresh. Chewing gum Formulation A-4 was subjected to accelerated aging for approximately 12 weeks. Trained panelists then compared the flavor of the control chewing gum with the Formulation A chewing gum of the present invention. The panelists found that the flavor in the control chewing gum degraded within about 2 weeks of storage while the degradation of flavor in the inventive gum was much slower and similar to the rate at which gum having peppermint flavor (but no acid) degrades, the equivalent of at least 18 months shelf life time. The panelists also found that the control chewing gum (containing free acid) had an unpalatable musty, bitter flavor, while the inventive product (containing the co-processed acid) has a cool flavor well-balanced with sweetness. Finally, the polishing achieved by the inventive chewing gum was found to be superior to the polishing obtained by commercially-available chewing gum which did not contain abrasive.

Example 3

The present example demonstrates the formation of a co-processed composition formed from mannitol and phosphoric acid. This co-processed composition was used in the chewing gum formulations A and B described in Example 1. Approximately 450 grams of mannitol powder (lot no. 3117G7, SPI Polyols, Inc., New Castle, DE) are placed in an eight-quart bowl of a Hobart mixer (model C-100, The Hobart Manufacturing Co., Troy, OH) equipped with a delta paddle having a dimension similar to the eight-quart Hobart bowl. In a beaker, about 58.82 grams of phosphoric acid (85% solution, Food Grade, lot no. 121163, Textile Chemical Co., Reading, PA) and about 500 grams of distilled water are mixed to form a uniform solution. With the Hobart mixer at a speed setting of about two, the solution of phosphoric acid and distilled water is added to the mannitol powder and mixed for about five minutes, or until semi-moist granules are formed having a popcorn-like shape with a diameter of about 2 inches or less.

The semi-moist granules are scraped out of the Hobart bowl using a plastic spatula and 30 are spread evenly onto a stainless steel drying tray. The granules are dried in an oven at a

temperature ranging from about 65.6°C to about 82.2°C for about 24 to 48 hours. The dried granules are cooled at ambient temperature (i.e., about 23°C to about 25°C) at a relative humidity of less than about 40%. The moisture content of the dried granules is less than about 0.5% when analyzed by Karl Fischer analysis (i.e., with a Karl Fischer Water Titration Unit, E.M. Science, Cincinnati, Ohio). The granules are poured into a Stoke Granulator grinder (model no. 43-4, Serial No. T39557, F. J. Stokes Corporation, Philadelphia, PA) and are reduced to a particle size which passes through U.S. Standard Sieve Screen Number 12.

5 Example 4

10 The present example demonstrates the formation of a co-processed composition formed from mannitol and malic acid. Approximately 450 grams of mannitol powder (lot no. 3117G7, SPI Polyols, Inc., New Castle, DE) are placed in an eight-quart bowl of a Hobart mixer (model C-100, The Hobart Manufacturing Co., Troy, OH) equipped with a delta paddle having a dimension similar to the eight-quart Hobart bowl. In a beaker, about 50 grams of malic acid (crystalline, Food Grade, lot no. 3/97, Bartek Ingredients, Inc., Ontario, Canada) and about 400 grams of distilled water are mixed to form a uniform solution. With the Hobart mixer at a speed setting of about two, the solution of malic acid and distilled water is added to the mannitol powder and mixed for about five minutes, or until semi-moist granules are formed having a popcorn-like shape with a diameter of about 2 inches or less.

15 20 The semi-moist granules are scraped out of the Hobart bowl using a plastic spatula and are spread evenly onto a stainless steel drying tray. The granules are dried in an oven at a temperature ranging from about 65.6°C to about 82.2°C for about 24 to 48 hours. The dried granules are cooled at ambient temperature (i.e., about 23°C to about 25°C) at a relative humidity of less than about 40%. The moisture content of the dried granules is less than about 0.5% when analyzed by the aforementioned Karl Fischer analysis. The granules are poured into a Stokes Granulator grinder (model no. 43-4, F. J. Stokes Corporation, Philadelphia, PA) and are reduced to a particle size which passes through U.S. Standard Sieve Screen Number 12.

25 30 While the present invention has been described with respect to what is presently considered to be preferred embodiments, it is to be understood that the invention is not limited to the disclosed embodiments. To the contrary, the invention is intended to cover various

modifications and equivalent arrangements included within the spirit and scope of the appended claims. The scope of the following claims is to be accorded the broadest interpretation so as to encompass all such modifications and equivalent formulations and functions.

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What is claimed is:

- 5 1. A method of minimizing the degradation of an acid-sensitive additive by at least one acidulent in a low-moisture comestible, confectionery, pharmaceutical or dentifrice product which contains the at least one acidulent, comprising preparing the product with the at least one acidulent in the form of a co-processed composition; wherein the co-processed composition is prepared by co-processing the at least one acidulent with at least one water-soluble crystalline compound independently chosen from the group consisting of sugar alcohols, sugars, and derivatives thereof.
- 10 2. The method of claim 1, wherein the product is chosen from the group consisting of chewing gum, bubble gum, instant beverages, frozen desserts, toothpaste, and dental floss.
- 15 3. The method of claim 2, wherein the product is a chewing gum.
4. The method of claim 1, wherein the at least one acidulent is an inorganic or organic acid or a salt thereof.
- 20 5. The method of claim 4, wherein the acid is an inorganic acid chosen from the group consisting of phosphoric acid, perchloric acid, nitric acid, hydrochloric acid, sulfuric acid, and boric acid.
6. The method of claim 4, wherein the acid is chosen from the group consisting of saturated and unsaturated hydroxy and non-hydroxy C₁ to C₆ mono-, di-, and tribasic carboxylic acids.
- 25 7. The method of claim 6, wherein the acid is chosen from the group consisting of citric acid, fumaric acid, tartaric acid, malic acid, succinic acid, ascorbic acid, glutaric acid, adipic acid, lactic acid, hydroxyacetic acid and mixtures thereof.
8. The method of claim 1, wherein the at least one water-soluble crystalline compound is a sugar alcohol.
- 30 9. The method of claim 8, wherein the sugar alcohol is chosen from the group consisting of mannitol, sorbitol, maltitol, xylitol, lactitol, erythritol, isomalt, and mixtures thereof.
10. The method of claim 9, wherein the sugar alcohol is mannitol.
11. The method of claim 1, wherein the at least one water-soluble crystalline compound is a sugar.

12. The method of claim 11, wherein the sugar is chosen from the group consisting of fructose, dextrose, maltose, lactose, D-tagatose, sucrose and longer chain saccharides and mixtures thereof.

13. The method of claim 1, wherein the comestible, confectionery, pharmaceutical or dentifrice product contains less than about 10 wt.% moisture.

14. The method of claim 13, wherein the comestible, confectionery, pharmaceutical or dentifrice product contains less than about 5 wt.% moisture.

15. The method of claim 13, wherein the comestible, confectionery, pharmaceutical or dentifrice product contains less than about 3 wt.% moisture.

16. A method of increasing salivation comprising the step of chewing a low-moisture comestible, confectionery, pharmaceutical or dentifrice product containing at least one acidulent; said product comprising the at least one acidulent in the form of a co-processed composition, wherein said co-processed composition is prepared by co-processing the at least one acidulent with at least one water-soluble crystalline compound independently chosen from the group consisting of sugar alcohols, sugars, and derivatives thereof.

17. The method of claim 16, wherein the product is chosen from the group consisting of chewing gum, bubble gum, instant beverages, frozen desserts, toothpaste, and dental floss.

18. The method of claim 17, wherein the product is chewing gum.

19. The method of claim 16, wherein the at least one acidulent is an inorganic or organic acid or salt thereof.

20. The method of claim 19, wherein the at least one acidulent is an inorganic acid chosen from the group consisting of phosphoric acid, perchloric acid, nitric acid, hydrochloric acid, sulfuric acid, and boric acid.

21. The method of claim 19, wherein the at least one acidulent is an organic acid chosen from the group consisting of saturated and unsaturated hydroxy and non-hydroxy C₁ to C₆ mono-, di-, and tribasic carboxylic acids.

22. The method of claim 21, wherein the at least one acidulent is chosen from the group consisting of citric acid, fumaric acid, tartaric acid, malic acid, succinic acid, ascorbic acid, glutaric acid, adipic acid, lactic acid, hydroxyacetic acid and mixtures thereof.

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23. The method of claim 16, wherein the at least one water-soluble crystalline compound is a sugar alcohol.

24. The method of claim 23, wherein the sugar alcohol is chosen from the group consisting of mannitol, sorbitol, maltitol, xylitol, lactitol, erythritol, isomalt, and mixtures thereof.

5 25. The method of claim 24, wherein the sugar alcohol is mannitol.

10 26. The method of claim 16, wherein the at least one water-soluble crystalline compound is an sugar.

15 27. The method of claim 26, wherein the sugar is chosen from the group consisting of fructose, dextrose, maltose, lactose, D-tagatose, sucrose and longer chain saccharides and mixtures thereof.

28. The method of claim 16, wherein the comestible, confectionery, pharmaceutical or dentifrice product contains less than about 10 wt.% moisture.

15 29. The method of claim 28, wherein the comestible, confectionery, pharmaceutical or dentifrice product contains less than about 5 wt.% moisture.

30. The method of claim 29, wherein the comestible, confectionery, pharmaceutical or dentifrice product contains less than about 3 wt.% moisture.

20 31. A method of removing or preventing the deposition of plaque on teeth, comprising regularly chewing gum; wherein the gum comprises a gum base, an abrasive, and at least one acidulent, wherein the at least one acidulent is in the form of a co-processed composition, and wherein the co-processed composition is prepared by co-processing the at least one acidulent with at least one water-soluble crystalline compound independently chosen from the group consisting of sugar alcohols, sugars, and derivatives thereof.

25 32. The method of claim 31, wherein the abrasive is chosen from the group consisting of calcined kaolin, calcined aluminum silicate, zirconium silicate, calcined and uncalcined talcs, $Mg_3Si_4O_{10}(OH)_2$, resin abrasives, barium sulfate, silica, alumina, calcium carbonate, pumice, sodium bicarbonate and mixtures thereof.

33. The method of claim 31, wherein the source of the at least one acidulent is an inorganic or organic acid or a salt thereof.

34. The method of claim 33, wherein the at least one acidulant is an inorganic acid chosen from the group consisting of phosphoric acid, perchloric acid, nitric acid, hydrochloric acid, sulfuric acid, and boric acid.

35. The method of claim 33, wherein the acid is an organic acid chosen from the group consisting of saturated and unsaturated hydroxy and non-hydroxy C₁ to C₆ mono-, di-, and tribasic carboxylic acids.

36. The method of claim 35, wherein the acid is chosen from the group consisting of citric acid, fumaric acid, tartaric acid, malic acid, succinic acid, ascorbic acid, glutaric acid, adipic acid, lactic acid, hydroxyacetic acid and mixtures thereof.

37. The method of claim 31, wherein the at least one acidulant is present in the product in an amount such that when 1 gram of the product is placed into 9 grams of deionized water and mixed well, the pH is decreased to a level in the range of from about 1 to about 5.

38. The method of claim 37, wherein the pH is decreased to a level in the range of from about 1 to about 4.5.

39. The method of claim 38, wherein the pH is decreased to a level in the range of from about 2.8 to about 3.2.

40. The method of claim 31, wherein the at least one water-soluble crystalline compound is a sugar alcohol.

41. The method of claim 40, wherein the sugar alcohol is chosen from the group consisting of mannitol, sorbitol, maltitol, xylitol, lactitol, erythritol, isomalt, and mixtures thereof.

42. The method of claim 41, wherein the sugar alcohol is mannitol.

43. The method of claim 31, wherein the at least one water-soluble crystalline compound is a sugar.

44. The method of claim 43, wherein the sugar is chosen from the group consisting of fructose, dextrose, maltose, lactose, D-tagatose, sucrose and longer chain saccharides and mixtures thereof.

45. The method of claim 31, wherein the chewing gum contains less than about 10 wt.% moisture.

46. The method of claim 45, wherein the chewing gum contains less than about 5 wt.% moisture.

47. The method of claim 46, wherein the chewing gum contains less than about 3 wt.% moisture.

5 48. A comestible, confectionery, pharmaceutical or dentifrice product comprising at least one acidulent in the form of a co-processed composition; wherein the co-processed composition is prepared by co-processing the at least one acidulent with at least one water-soluble crystalline compound independently chosen from the group consisting of sugar alcohols, sugars, and derivatives thereof.

10 49. The product of claim 48, wherein the product is chosen from the group consisting of chewing gum, bubble gum, instant beverages, frozen desserts, toothpaste, and dental floss.

50. The product of claim 49, wherein the product is chewing gum.

51. The product of claim 48, wherein the at least one acidulent is an inorganic or organic acid or a salt thereof.

15 52. The product of claim 51, wherein the acid is an inorganic acid chosen from the group consisting of phosphoric acid, perchloric acid, nitric acid, hydrochloric acid, sulfuric acid, and boric acid.

20 53. The product of claim 51, wherein the acid is an organic acid chosen from the group consisting of saturated and unsaturated hydroxy and non-hydroxy C₁ to C₆ mono-, di-, and tribasic carboxylic acids.

54. The product of claim 53, wherein the acid is chosen from the group consisting of citric acid, fumaric acid, tartaric acid, malic acid, succinic acid, ascorbic acid, glutaric acid, adipic acid, lactic acid, hydroxyacetic acid and mixtures thereof.

25 55. The product of claim 48, wherein the at least one water-soluble crystalline compound is a sugar alcohol.

56. The product of claim 55, wherein the sugar alcohol is chosen from the group consisting of mannitol, sorbitol, maltitol, xylitol, lactitol, erythritol, isomalt, and mixtures thereof.

57. The product of claim 56, wherein the sugar alcohol is mannitol.

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58. The product of claim 48, wherein the at least one water-soluble crystalline compound is a sugar.

59. The product of claim 58, wherein the sugar is chosen from the group consisting of fructose, dextrose, maltose, lactose, D-tagatose, sucrose and longer chain saccharides and mixtures thereof.

60. The product of claim 48, wherein the product contains less than about 10 wt.% moisture.

61. The product of claim 60, wherein the product contains less than about 5 wt.% moisture.

62. The product of claim 60, wherein the product contains less than about 3 wt.% moisture.

63. A comestible, confectionery, pharmaceutical or dentifrice product comprising an abrasive and at least one acidulent; wherein the at least one acidulent is in the form of a co-processed composition prepared by co-processing the at least one acidulent with at least one water-soluble crystalline compound independently chosen from the group consisting of sugar alcohols, sugars, and derivatives thereof.

64. The product of claim 63, wherein the product is chosen from the group consisting of chewing gum, bubble gum, instant beverages, frozen desserts, toothpaste, and dental floss.

65. The product of claim 64, wherein the product is chewing gum.

66. The product of claim 63, wherein the source of the at least one acidulent is an inorganic or organic acid or a salt thereof.

67. The product of claim 66, wherein the acid is an inorganic acid chosen from the group consisting of phosphoric acid, perchloric acid, nitric acid, hydrochloric acid, sulfuric acid, and boric acid.

68. The product of claim 66, wherein the acid is an organic acid chosen from the group consisting of saturated and unsaturated hydroxy and non-hydroxy C₁ to C₆ mono-, di-, and tribasic carboxylic acids.

69. The product of claim 68, wherein the acid is chosen from the group consisting of citric acid, fumaric acid, tartaric acid, malic acid, succinic acid, ascorbic acid, glutaric acid, adipic acid, lactic acid, hydroxyacetic acid and mixtures thereof.

70. The product of claim 63, wherein the at least one water-soluble crystalline compound is a sugar alcohol.

71. The product of claim 70, wherein the sugar alcohol is chosen from the group consisting of mannitol, sorbitol, maltitol, xylitol, lactitol, erythritol, isomalt, and mixtures thereof.

5 72. The product of claim 71, wherein the sugar alcohol is mannitol.

73. The product of claim 63, wherein the at least one water-soluble crystalline compound is a sugar.

74. The product of claim 73, wherein the sugar is chosen from the group consisting of fructose, dextrose, maltose, lactose, D-tagatose, sucrose and longer chain saccharides and mixtures thereof.

10 75. The product of claim 63, wherein the product contains less than about 10 wt.% moisture.

76. The product of claim 75, wherein the product contains less than about 5 wt.% moisture.

77. The product of claim 75, wherein the product contains less than about 3 wt.% moisture.

20 78. A co-processed composition consisting essentially of at least one water-soluble crystalline compound selected from the group consisting of sugar alcohols, sugars and derivatives thereof, and at least one acidulent.

79. The co-processed composition of claim 78, wherein the at least one acidulent is selected from the group consisting of citric acid, fumaric acid, lactic acid, tartaric acid and adipic acid.

25 80. The co-processed composition of claim 78, wherein the at least one acidulent is selected from the group consisting of phosphoric acid and malic acid.

81. The co-processed composition of claim 78, wherein said co-processed composition consists essentially of about 80-99 weight percent of said at least one water-soluble crystalline compound and 1-20 weight percent of said at least one acidulent, based on the total weight of said at least one water-soluble crystalline compound and the at least one acidulent.

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82. The co-processed composition of claim 78, wherein said co-processed composition is in the form of granules or agglomerates.

83. The co-processed composition of claim 78, wherein said co-processed composition is in the form of powder.

5 84. A process of making a co-processed composition consisting essentially of at least one water-soluble crystalline compound selected from the group consisting of sugar alcohols, sugars and derivatives thereof, and at least one acidulant, comprising the following steps:

- a) mixing said at least one water-soluble crystalline compound, said at least one acidulant and water to form a mixture;
- b) forming said mixture into granules or agglomerates and
- c) removing at least a portion of the water from said granules or agglomerates.

10 85. The process of claim 84, wherein the at least one acidulant is selected from the group consisting of citric acid, fumaric acid, lactic acid, tartaric acid and adipic acid.

15 86. The process of claim 84, wherein the at least one acidulant is selected from the group consisting of phosphoric acid and malic acid.

20 87. The process of claim 84, wherein said forming occurs in a wet granulation or agglomeration process.

25 88. Pharmaceutical product, food product or confectionery product containing the co-processed composition of claim 78.

89. A pharmaceutical product, food product or confectionery product containing the co-processed composition of claim 80.

90. A chewing gum containing the co-processed composition of claim 78.

25 91. A chewing gum containing the co-processed composition of claim 80.

92. A pharmaceutical product, food product or confectionery product that contains at least one alkaline ingredient and the co-processed composition of claim 78.

93. A chewing gum that contains at least one acid-sensitive additive and the co-processed composition of claim 78.

30 94. A hard candy containing the co-processed composition of claim 78.

95. A jam, jelly or other soft filling for a food product or confectionery product that contains the co-processed composition of claim 78.

96. A baked product that contains the co-processed composition of claim 78.

5 97. The co-processed composition of claim 78, wherein the at least one water-soluble crystalline compound is mannitol.

98. The process of claim 84, wherein the at least one water-soluble crystalline compound is mannitol.

99. A co-processed composition consisting essentially of mannitol, water and at least one acidulant selected from the group consisting of phosphoric acid and malic acid, wherein said mannitol is present in an amount of from about 80-99% by weight of the co-processed composition, said water is present in an amount of about 0.01% to 2% by weight of the co-processed composition and the remainder of the co-processed composition is said at least one acidulant.

100. The method of claim 3, wherein the at least one acidulant is phosphoric acid, the at least one water soluble crystalline compound is mannitol and the acid-sensitive additive is a flavor.

101. The method of claim 100, wherein the chewing gum further contains kaolin.

102. The method of claim 18, wherein the at least one acidulant is phosphoric acid and the at least one water-soluble crystalline compound is mannitol and wherein the chewing gum further contains an acid-sensitive flavor.

103. The method of claim 102, wherein the chewing gum further contains kaolin.

104. The method of claim 42, wherein the at least one acidulant is phosphoric acid, the abrasive is kaolin and wherein the gum further contains an acid-sensitive flavor.

105. The product of claim 50, wherein the at least one acidulant is phosphoric acid and the at least one water-soluble crystalline compound is mannitol and wherein the chewing gum further contains an acid-sensitive flavor.

106. The product of claim 105, wherein the chewing gum further contains kaolin.

107. The product of claim 65, wherein the at least one acidulant is phosphoric acid and the at least one water-soluble crystalline compound is mannitol and wherein the chewing gum further contains an acid-sensitive flavor.

108. The product of claim 107, wherein the chewing gum further contains kaolin.
 109. A chewing gum containing the co-processed composition made by the process of claim 84.
 110. The chewing gum of claim 109, wherein the at least one acidulant is phosphoric acid, the at least one water-soluble crystalline compound is mannitol and wherein the chewing gum further contains an acid-sensitive flavor.
 111. The process of claim 110, wherein the chewing gum also contains kaolin.
 112. The chewing gum of claim 93, wherein the at least one acidulant is phosphoric acid, the at least one water-soluble crystalline compound is mannitol and the acid-sensitive additive is a flavor.
 113. The process of claim 112, wherein the chewing gum also contains kaolin.
 114. A chewing gum containing the co-processed composition of claim 99.

COMBINED DECLARATION AND POWER OF ATTORNEY

Attorney Docket No.

SPI/HER

As below named inventors, we hereby declare that:

Our residence, post office address and citizenship are as stated below next to our names,

We believe we are the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of subject matter which is claimed and for which a patent is sought on the invention entitled "CO-PROCESSED COMPOSITIONS OF ACIDS AND WATER SOLUBLE CRYSTALLINE COMPOUNDS AND RELATED PRODUCTS AND METHODS"

the specification of which

(check one) is attached hereto.

was filed on May 19, 1999 as Application Serial No. PCT/US99/11072.

Express Mail No. _____, as Serial No. not yet known,

We hereby state that we have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

We acknowledge the duty to disclose to the Office all information known to us to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

We hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority Claimed

<u>(Number)</u>	<u>(Country)</u>	<u>(Day/Month/Year Filed)</u>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<u>(Number)</u>	<u>(Country)</u>	<u>(Day/Month/Year Filed)</u>	<input type="checkbox"/> Yes	<input type="checkbox"/> No

We hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112. We acknowledge the duty to disclose to the Office all information known to us to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application

<u>09/080,970</u> (Application Serial No.)	<u>MAY 19, 1998</u> (Filing Date)	<u>PENDING</u> (Status) (patented, pending, abandoned)
<u>(Application Serial No.)</u>	<u>(Filing Date)</u>	<u>(Status)</u> (patented, pending, abandoned)
<u>(Application Serial No.)</u>	<u>(Filing Date)</u>	<u>(Status)</u> (patented, pending, abandoned)

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventors, we hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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